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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,954	03/19/2004	Marise S. Gottlieb		8077

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EXAMINER	
CORDERO GARCIA, MARCELA M	
ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
02/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/804,954	**Applicant(s)** GOTTLIEB, MARISE S.
	Examiner Marcela M. Cordero Garcia	**Art Unit** 1654

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 January 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-4 and 6-18*.
   Claim(s) withdrawn from consideration: *8-18*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 3. NOTE: Instant claim 1 is drawn to a method for controlling chronic inflammation in an individual having Metabolic Syndrome comprising adminsitering to said individual an effective dosage of a pharmaceutical composition selected from the group consisting of YG-Product, YGG-Product, Purefied Leukocyte Dialysate Subfraction and a combination thereof. Applicant Argues that the examiner unreasonably interpreted chronic inflammation in an individual having Metabolic Syndrome as any type of chronic inflammation in an individual having Metabolic Syndrome. MPEP 2111 states that: "The Patent and Trademark Office (PTO) determines the scope of claims in pattent applications no solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art... Indeed, the rules of the PTO requiere that application claims must "confromr to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the calims may be ascertainable by reference to the description". Here, wis respect to "chroninc inflammation in an individual having Metabolic Syndrome", the examiner argued that the origin of chronic inflammation is not specified, thus, the claims read upon treating any type of chronic inflammation in an individual having metabolic syndrome". The examiner's interpretationn is unreaasonable in view of the ordinary skilled person in the art, solely on the basis of the claim language, but not upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art". The title of the present application is "Treatment of Type II Diabetes and Other Conditions associated with the metabolic Syndrome, (Syndrome X), a Disease of the Innate Immune System, with a Unique Immunomodulator". The present specification also states that "The present invention relates to a method for treating individuals having inflammation or preventing inflammation in individuals at risk for inflammation, more specifically individuals with chronic inflammation as evidenced by elevated acute phase reactants including C-reactive protein and serum fibrinogen, elevated platelet count or platelet activity, elevated blood glucose or any component or combination of componets of the metabolic syndrome, from progressing to the natural outcome of the syndrome, such outcome being diabetes mellitus, coronary artery disease, and related complications of diabetes mellitus. Also, one of ordinary skill would construe "chronic inflammation in an individual having metabolic syndrome" to mean that the chronic inflammation is associated with metabolic cyndrome, otherwise the phrase "in an individual having Metabolic syndrome' is meaningless. Applicant's arguments have been carefully considered but not deemed persuasive because the definition of chronic inflammation does not require the individual to have a metabolic syndrome, i.e., it is defined as inflammation as evidenced by elevated acute phase reactants such as C-reactive protein and serum fibrinogen, elevated platelet count or platelet activity, elevated blood glucose or any component or combination of componets of the metabolic syndrome, which therefore includes rheumatoid arthritis which is characterized by elevated C-protein reactive. 2) The examiner failed to show that all the claim limitations were taught or suggested by the prior art. The inventor of Gottlieb was the husband and professional colleague of the inventor. When Gottlieb teaches diabetes means diabetes type I. The examiner is taking the reference to diabetes out of proper context. The reference to Persselin is also not proper. The cause of rheumatoid arthritis is an autoimmune reaction in which the joints are attacked by the patient's own immune system, resulting in damage to the joints. Such destruction subsequently results in chronic inflammation from rubbing of unprotected bone. Gottlieb, in his earlier patents discusses treatment of the autoimmune reaction, NOT the subsequent inflammation. What is important is for the examiner to understand that inflammation may be caused by many things. Applicant's arguments have been carefully considered but not deemed persuasive because the the claims have not been amended to control chronic inflammation associated exclusively with metabolic syndrome. 3) The metabolic syndrome is a complex constellation of symptoms and conditions which tend to appear in a cluster. The metabolic syndrome is not equivalent to any tipe of diabetes mellitus or obesity, variablitity of the exampression of the metabolic syndrome, other than for inflammation, there is no universal treatment that has been found to treat it. A careful search of Gottlieb's patents reveals that he did not teach in any way that the technology of the instant application would treat chronic inflammation. Applicant's arguments have been carefully considered but not deemed persuasive because: As applicant states: the method treats "chronic inflammation", which reads upon rheumatod arthritis as drafted, and because the instant method steps do not require that the individual be "in need thereof", which reads upon prevention of the inflammation. In addition, KSR forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness. See the recent Board decision Ex parte Smith, --USPQ2d--, slip op. at 20, (Bd. Patt. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2s at 1396) (available at http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf). It has been held that under KSR that "obvious to try" may be an appropriate test under 103 The Supreme Court stated in KSR:

When there is motivation "to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, ___, 82 USPQ2d 1385, 1397 (2007).

The "problem" facing those in the art was the treatment of chronic inflammation due to diabetes, and there were a limited number of methodologies available to do so. The skilled artisan would have had reason to try these methodologies with the reasonable expectation that at least one would be successful. In the instant case the instantly claimed products were taught as useful to treat chronic inflammation and diabetes type I by the prior art as set forth above. Thus, treating chronic inflammation in a diabetes type II patient using an antiinflammatory agent useful for treating diabetes is not a "the product not of innovation but of ordinary skill and common sense," leading to the conclusion that invention is not patentable as it would have been obvious.
In addition, KSR forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness. See the recent Board decision Ex parte Smith, --USPQ2d--, slip op. at 20, (Bd. Patt. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2s at 1396) (available at http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).